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| APPLICATION NO.   | FILING DATE              | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |  |
|---|--------------------------|-----------------------|-------------------------------|------------------|--|
| 10/551,619  | 12/22/2006               | Paul Taylor Martin 00 | 0015-022US1/SD2002-161-M 5898 |                  |  |
| 26138<br>Joseph R. Bake                                       | 7590 01/06/200<br>r. APC | 9                     | EXAMINER                      |                  |  |
| Gavrilovich, Do   | odd & Lindsey LLP        |                       | WANG, C                       | WANG, CHANG YU   |  |
| 4660 La Jolla Village Drive, Suite 750<br>San Diego, CA 92122 |                          | ı                     | ART UNIT                      | PAPER NUMBER     |  |
| <i>C 7</i>  |                          |                       | 1649                          |                  |  |
|   |                          |                       |                               |                  |  |
|   |                          |                       | MAIL DATE                     | DELIVERY MODE    |  |
|   |                          |                       | 01/06/2009                    | PAPER            |  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)            |  |  |  |  |
|--|--|-------------------------|--|--|--|--|
| Office Action Comment  | 10/551,619   | MARTIN, PAUL TAYLOR     |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit                |  |  |  |  |
|  | Chang-Yu Wang  | 1649                    |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |  |                         |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                         |  |  |  |  |
| Status   |  |                         |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>30 Se</u>   | intember 2005  |                         |  |  |  |  |
|  |  |                         |  |  |  |  |
| · <u> </u>   | This action is <b>FINAL</b> . 2b) This action is non-final.  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                         |  |  |  |  |
|  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                         |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1933 C.D. 11, 433 C.G. 213.  |  |                         |  |  |  |  |
| Disposition of Claims  |  |                         |  |  |  |  |
| 4) Claim(s) <u>1-26</u> is/are pending in the application.   | 4) Claim(s) 1-26 is/are pending in the application.  |                         |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                         |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |                         |  |  |  |  |
| 6) Claim(s) is/are rejected.   |  |                         |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |                         |  |  |  |  |
| 8) Claim(s) <u>1-26</u> are subject to restriction and/or e  | lection requirement  |                         |  |  |  |  |
| 6) Claim(s) 1-20 are subject to restriction and/or election requirement.   |  |                         |  |  |  |  |
| Application Papers   |  |                         |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |  |                         |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.   |  |                         |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |                         |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |                         |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                         |  |  |  |  |
|  |  |                         |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                         |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ul>   |  |                         |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |                         |  |  |  |  |
|  |  |                         |  |  |  |  |
| Attachment(s)  |  |                         |  |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)         <ul> <li>Paper No(s)/Mail Date</li> </ul> </li> </ol>   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: Notice of seg   | te<br>atent Application |  |  |  |  |
| . , ,  | · <del></del>  |                         |  |  |  |  |



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## Sequence Non-compliance

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1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence identification has been provided for the sequences presented on p.9, [0030]-[0031]; p.20, [0059]; p.21, [0061]-[0062]; p.22, [0063]; p. 27, [0074]; p.29, [0078]; p. 31, [0082]; p.33, [0087]; p. 34, [0089], [0091]; p. 35, [0094]; p. 36; p. 37 and claims 1-2 of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO: ) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as nonresponsive, and may result in Art Unit: 1649

abandonment of this application. Note further that a new CRF, paper copy and appropriate statement that these are the same and no new mater exists is still required.

## Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I-VI, claim(s) 1-12 and 19-23 (all in part), drawn to a polypeptide of SEQ ID NO: 1-6 and a hybrid molecule derived from SEQ ID NO:1-6.

Groups VII-XII, claims 13 and 24-25 (all in part), drawn to a method of treating or diagnosing Alzheimer's or a neurodegenerative disease using SEQ ID NO:1-6 or a hybrid molecule derived from SEQ ID NO:1-6.

Groups XIII-XVIII, claims 14-18 (all in part), drawn to a nucleic acid, vector, host cell for SEQ ID NO:1-6.

Groups XIX-XXIV, claim 26 (all in part), drawn to an anti-idiotype antibody binding to SEQ ID NO:1-6.

3. The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The technical features of Groups I-VI (polypeptides and hybrid molecules derived from polypeptides), XIII-XVIII (DNAs, vectors and host cells) and XIX-XXIV (antibodies) are drawn to structurally different products, which do not require each other for their practice and do not share the same or a corresponding technical feature. Groups VII-XII are drawn to methods of treating or diagnosing Alzheimer's disease or a neurodegenerative disease, which use different polypeptides and materials and do not require each other for their practice and do not share the same technical feature.

Therefore, the above Inventions do not share a common special technical feature as they comprise different steps and utilize different products, which demonstrates that each method has a different mode of operation and use of structurally and functionally divergent materials. Accordingly, Groups I-XXIV are not so linked by the same or a corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

## Species Election

- 4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
  - i. If Group I is elected, Applicant is required under PCT Rule 13.2 to elect a single disclosed molecular embodiment of the integer selected from A) 1-20, B) 1-15, C) 1-10 or D) 1-5 as recited in claims 1-2, and 5-7 for prosecution on the merits to

allowable.

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- 5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The technical features of these species are different because each specific species differs with respect to its composition and structures. Consequently the responses of cells to different biomolecules are also different. Therefore, these species do not share a common corresponding technical feature; and thus lack unity of invention.
- 6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-XXIV and a single species from group i that is applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group and species.

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8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christine J Saoud/ Primary Examiner, Art Unit 1647

/CYW/ Chang-Yu Wang, Ph.D. December 30, 2008